K130828

JAN 13 2014

Section 5. 510(k) Summary

510(k) SUMMARY

A 510(k) summary has been prepared in accordance with the requirements of 21 CFR 807.92.

Submitter:	Curative Medical Inc. 3227 Kifer Road Santa Clara, CA 95051 Establishment Number: 3008361782
Company Contact Person: Phone: Fax: Email:	Cuong Tran, R/D Director (408) 414-2188 (408) 413-3000 ctran@curativemedical.com
Submission Correspondent: Address: Phone: Email:	Amy McKinney, Regulatory Affairs Consultant 6518 Tamarind Sky Ln., Fulshear, TX 77441 (979) 236-1622 amckinney29@att.net
Device Name:	Curasa AUTO CPAP with Heated Humidifier System
Device Classification Name:	Non-continuous ventilator (BZD) 21 CFR 868.5905
Predicate Devices:	Respironics Remstar Auto CPAP (K012554) Curasa CPAP SD (K123897)
Preparation Date:	March 25, 2013 Revised December 20, 2013 Revised December 29, 2013

Device Description:

The Curasa AUTO CPAP System with heated humidifier is used on adult patients for treatment of obstructive sleep apnea (OSA). The Auto CPAP system provides a stable continuous positive airway pressure (CPAP). The Auto mode detects breathing phenomena (e.g. snore, hypopnea) and automatically adjusts the delivered pressure. The humidifier provides warm, humidified air for comfort to the patient, reducing nose and airway dryness. The Curasa AUTO CPAP system includes the following accessories: a power supply, a Patient Air Circuit, and a U-tube connection between CPAP and humidifier. All of the accessories provided with the Curasa AUTO CPAP are identical to those provided with the predicate Curasa CPAP SD (K123897).

The Auto CPAP system has been modified based Curasa CPAP SD (K123897) hardware and software. The design of the humidifier and humidifier interface is identical to the referenced predicate device (Curasa CPAP SD, K123897). The basic function and performance characteristics of Curasa AUTO CPAP are similar to the referenced predicate device (Curasa

CPAP SD K123897). The Auto mode of operation is similar to the referenced predicate, Respironics Remstar Auto CPAP (K012554).

The Curasa AUTO CPAP with heated humidifier system has the following similarities to the previous cleared predicate devices:

- Same intended use
- Same operating principle
- Similar technologies
- Same patient contacting materials

Parameter	Respironics Remstar Pro Auto CPAP system (K012554)	Curative Medical Inc. Curasa CPAP SD (K123897)	Curative Medical Inc. Curasa AUTO CPAP (Proposed Device)
CPAP Device:			
Device Size (cm)	24 x 17 x 12	17 x 11.8 x 9.7	17 x 11.8 x 9.7
Weight (kg)	<1.8	1.4	1.4
Mode of Operation	CPAP and Auto	CPAP	CPAP and Auto
Indication for Use	The Respironics REMstar Auto System is a CPAP (continuous Positive Airway Pressure) device designed for the treatment of adult Obstructive Sleep Apnea (OSA) only.	The Curasa CPAP SD is designed for the treatment of Obstructive Sleep Apnea only in spontaneously breathing patients weighing >30 kg. It is intended to be used in the home or hospital/institutional environment.	The Curasa AUTO CPAP with Heated Humidifier System is designed for the treatment of Obstructive Sleep Apnea only in spontaneously breathing patients weighing >30 kg. It is intended to be used in the home or hospital/institutional environment.
Product Use, Transport, Storage			
Operation (°C)	5 to 35	5 to 35	5 to 35
Transport & Storage (°C)	-20 to 60	-20 to 60	-20 to 60
Atmosphere Pressure (Operation)	83 to 102 kPa	70 to 106 kPa	70 to 106 kPa
Mode of Operation	Continuous	Continuous	Continuous
Type of Protection Against Electric Shock	Class II Equipment	Class II Equipment	Class II Equipment
Degree of Protection Against Electric Shock	Type BF Applied Part	Type B Applied Part	Type BF Applied Part

Parameter	Respironics Remstar Pro Auto CPAP system (K012554)	Curative Medical Inc. Curasa CPAP SD (K123897)	Curative Medical Inc. Curasa AUTO CPAP (Proposed Device)
Degree of Protection Against Ingress of Water	IPX1	IPX1	IPX1
Pressure Range (cm H2O)	4 - 20	4 - 20	4 - 20
Pressure Stability (cm H2O), as measured by ISO 17510-1	4-20 cm H2O, +/- 1.0 cm H2O	4-20 cm H20 +/- 2.0 cm H20 ISO17510 compliant	4-20 cm H20 +/- 2.0 cm H20 ISO17510 compliant
Maximum Flow (LPM), as measured by ISO 17510-1	35	35	35
Humidifier			
Water reservoir	415 ml	240 ml	240 ml
Weight	2.2 lbs	< 0.9 lbs	< 0.9 lbs
Power Consumption			
Electrical shock protection:	Class II	Class II	Class II
Drip Proof Equipment	IPX1	IPX1	IPX1
Heater Setting	1 - 5	continuous	continuous

Intended Use:

The Curasa AUTO CPAP (Continuous Positive Airway Pressure) with heated humidifier system is intended for the treatment of Obstructive Sleep Apnea only in spontaneously breathing patients weighing >30 kg. It is for use in the home or hospital /institutional environment.

Contraindications:

- Bullous Lung Disease
- Pathologically Low Blood Pressure
- Bypassed Upper Airway
- Pneumothorax
- Pneumocephalus has been reported in a patient using nasal Continuous Positive Airway Pressure. Caution should be used when prescribing CPAP for susceptible patients such as those with: cerebral spinal fluid (CSF) leaks, abnormalities of the cribriform plate, prior history of head trauma, and/or pneumocephalus.
- The use of positive airway pressure therapy may be temporarily contraindicated if you exhibit signs of sinus or middle ear infection. Not for use with patients whose upper airways are by-passed.

Summary of Performance Data and Substantial Equivalence:

The Curasa AUTO CPAP with heated humidifier system was designed and verified in accordance with the risk analysis and product requirements. All tests confirmed the products met the pre-defined acceptance criteria. Curative Medical Inc. has determined that the Curasa AUTO CPAP is substantially equivalent to the predicate Respironics Remstar Auto CPAP for treatment of OSA in adults. The Curasa AUTO CPAP with heated humidifier system has been tested and shown to be compliant with the following standards documents:

1. IEC 60601-1-1:1988 + A1:1991 + A2:1995 - Medical Electrical equipment - Part 1: General requirement for Safety
2. IEC 60601-1-2:2007 - Medical Electrical equipment – Part 1-2: General requirement for Safety – Collateral Standard: Electromagnetic compatibility – Requirements and tests
3. EN ISO 8185:2007 - Respiratory Tract humidifiers for medical use – Particular requirements for respiratory humidifier systems
4. EN ISO 17510:2007 - Sleep Apnoea Breathing therapy – Part 1: Sleep apnoea breathing therapy equipment
5. ISO 10993-3:2003 - Biological Evaluation of Medical Devices – Part 3: Genotoxicity, Carcinogenicity and Reproductive Toxicity
6. ISO 10993-5: 2009 - Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
7. ISO 10993-6:2007 - Biological Evaluation of Medical Devices – Part 6: Test for local effect after implantation
8. ISO 10993-10:2010 – Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization
9. ISO 10993-12:2007 – Biological Evaluation of medical devices Part 12: Sample Preparation and reference materials
10. IEC 62304:2006 – Medical Device Software – Software Life Cycle Process
11. IEC 60068-2-6:2007 - Environmental Testing – Test FC: Vibration (sinusoidal)
12. IEC 60068-2-34:1973 - Environmental Testing – Test FC: Vibration (Random)
13. IEC 60068-2-27:2008 - Basic Environmental Testing Procedure: Test Ea and guidance: Shock

The following testing was conducted to demonstrate the performance of Curasa AUTO CPAP, is substantially equivalent to its predicate devices in its intended environment:

Design Verification Test	Result
Sound Testing	Pass
VOC and PM2.5 Testing	Pass
Shock and Vibration Testing	Pass
Predicate Comparison Testing	Pass
System and User Interface Testing	Pass
IFU Validation Testing	Pass
ESD / EMC / EMI	Pass
Safety Testing (IPX1 / ESD)	Pass
Software Verification Testing	Pass

Test data leveraged from the predicate device, Curasa CPAP SD (K123897) includes the following:

- Reliability Test
- Packaging Test
- Humidity ISO 8185 Test
- Biocompatibility Tests

This 510(k) submission presents the results of the testing and detailed descriptions to demonstrate that Curasa AUTO CPAP with heated humidifier system is substantially equivalent to the Respironics Remstar Auto CPAP System (K012554) and Cursasa CPAP SD (K123897).

Clinical Data:

Curative Medical conducted a clinical study at two (2) hospitals in China enrolling sixty (60) adult patients diagnosed with Obstructive Sleep Apnea (OSA) to evaluate the Curasa AUTO CPAP system compared to the predicate Respironics Auto CPAP. Selected OSA patients all underwent 3 nights of study with the PSG (polysomngram); the 1st night of PSG diagnosing; then randomly entered either the trial group or the control group the 2nd night; following the 3rd night to complete the alternate group study. Each patient was evaluated by AHI (Apnea/hypopnea Index); minimum SpO2 (Pulse Oximeter Oxygen Saturation) and average SpO2 recorded by PSG throughout the 3-night study. P-values were calculated using the t-test for before and after treatment groups and for trial and control groups. Results showed that the Curasa AUTO CPAP is effective and that there is no statistical difference between the Curasa AUTO CPAP and the predicate Respironics Auto CPAP device.

Conclusion:

The minor differences between the Curasa AUTO CPAP and its predicate devices outlined in the tables above do not raise new questions of safety and effectiveness. The information and data provided in this 510(k) notification establishes that the Curasa AUTO CPAP with heated humidifier system is substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 13, 2014

Curative Medical, Inc.
c/o Ms. Amy E. McKinney
Regulatory Affairs Consultant
6518 Tamarind Sky Ln
Fulshear, TX 77441

Re: K130828
Trade/Device Name: Curasa AUTO CPAP with Heated Humidifier System
Regulation Number: 21 CFR 868.5905
Regulation Name: Non-continuous ventilator
Regulatory Class: II
Product Code: BZD
Dated: December 20, 2013
Received: December 23, 2013

Dear Ms. McKinney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

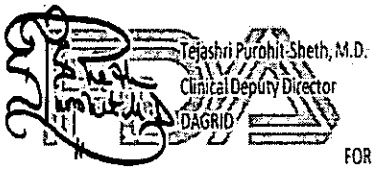
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



FOR

Erin Keith M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K130828

Device Name
Curasa AUTO CPAP with Heated Humidifier System

Indications for Use *(Describe)*
The Curasa AUTO CPAP (Continuous Positive Airway Pressure) with heated humidifier system is intended for the treatment of Obstructive Sleep Apnea only in spontaneously breathing patients weighing >30 kg. It is for use in the home or hospital /institutional environment.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Anya C. Harry -S
2014.01.10
12:38:55 -05'00'

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."